JUL 15 2003

K031250

LHASA MEDICAL, INC.

234 Libbey Parkway, Weymouth, MA 02189 (781) 340-1071 fax: 781-659-9916
(or fax: 781-335-6296)

April 17, 2003 Page 6a

PRE-MARKET NOTIFICATION 510(k) SUMMARY
(As Required by 21 CFR 807.92)

(a)(1)

Submitter:	Lhasa Medical, Inc 234 Libbey Parkway Weymouth, MA 02189
Contact Person:	Kyung P. Riihimaki
Date Summary Prepared:	April 17, 2003

(a)(2)

Device Trade Name:	DBC Press Acupuncture Needles
Common or Usual Name:	Acupuncture Needles
Device Classification Name:	Needle, Acupuncture, Single Use
Classification:	Class II
510(k) Number:	K-

(a)(3) Substantially Equivalent

This device is substantially equivalent in design and performance to other brands of acupuncture needles which were in commercial distribution in the USA prior to May 28, 1976. These acupuncture needles are also substantially equivalent to other acupuncture needles which have received approval through the 510(k) premarket notification process.

These include the following:

SEIRIN Pyonex Press Acupuncture Needles K-970254

..... continued on next page

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PRE-MARKET NOTIFICATION 510(k) SUMMARY ..... continued from previous page

(a)(4) Description
Description of DBC Press Acupuncture Needles.
DBC Press Acupuncture Needles are small, sterile disposable, surgical s/steel, press type acupuncture needles. The 2.0 mm dia ring handle is continous with the 1.0 mm or 1.5 mm long needle body. These needles are supplied in sealed packages on polystyrene plastic holders.

(a)(5) Indications for Use
Acupuncture needles are used to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

(a)(6) Technological Characteristics
DBC Press Acupuncture Needles are used in the same manner and have the same technological characteristics as the predicate device(s) identified in paragraph (a)(3). These needles use the same needle body lengths and gauges (needle thickness); handle design; method of insertion; and use the same packaging methods as these predicate devices.

(b)(1)(2)(3)
Substantial equivalence is not based on an assessment of performance data.

(c) This summary includes these 2 pages in total.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Kyung P. Riihimaki President
LHASA MEDICAL, Incorporated
234 Libbey Parkway
Weymouth, Massachusetts 02189

Re: K031250
Trade/Device Name: DBC Press Acupuncture Needles
Regulation Number: 880:5580
Regulation Name: Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: June 11, 2003
Received: June 13, 2003

Dear: Riihimaki

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031250

510(k) Number (if known): K-

Device Name: DBC Press Acupuncture Needles

Indications for Use

These acupuncture needles are used to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluations (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031250

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)